REMARKS

Applicants have received and reviewed an Office Action dated March 27, 2003. Applicants request entry of this Amendment and reconsideration of the rejection of the claims.

Applicants have canceled claims 1, 8, 9, 11, 19 and 20 without prejudice or disclaimer. Applicants reserve the right to file a continuation application directed to the subject matter of these claims.

Applicants have amended claims 33, 36, 41, and 43 to clarify the subject matter of the claims. Applicants submit the amendment to the claims is supported throughout the specification including at page 22, lines 17-24; and page 97, line 10 to page 98, line 4.

Applicants have added new claims 45-51. Applicants submit the new claims are supported throughout the specification including at page 11, line 16 to page 12; page 12, line 22 to page 14, line 18; page 22, lines 17-24; page 56, lines 13-29; and page 97, line 10 to page 98, line 4.

Petition for Extension of Time

It is noted that a three-month petition for extension of time is necessary to provide for the timeliness of the response. A request for such an extension is made extending the time for response from June 27, 2003 to September 27, 2003.

35 U.S.C. 102

Applicants acknowledge the withdrawal of the 35 U.S.C. 102(e) rejection of claims 1, 8, 9, 11, 19, and 20 as anticipated by U.S. Patent No. 5, 731, 168, U.S. Patent No. 5, 808,706, or U.S. Patent No. 5,821,333.

Obviousness Type Double Patenting

Applicants acknowledge the withdrawal of the obviousness type double patenting rejection of claims 1, 8, 9, 11, 19, and 20 over claims of U.S. Patent No. 5, 731, 168, U.S. Patent No. 5, 808,706, and U.S. Patent No. 5,821,333.

35 U.S.C. § 103

1) **Claims 1, 8, 9, 11, 19, 20, 33-38, and 41-44 stand rejected under 35 U.S.C. § 103 as unpatentable over Mallender et al. as evidenced by Gulliver, et al. in view of U.S. Pat. Nos. 5,731,168-A, 5,807,706-A, and 5,821,333-A.**

Applicants have canceled claims 1, 8, 9, 11, 19 and 20, rendering the rejection of these claims moot. Applicants respectfully traverse the rejection of claims 33-38 and 41-44.

In order to establish a prima facie case of obviousness, three basic criteria must be met, namely: 1) the references when combined must teach or suggest all of the claim limitations; 2) suggestion or motivation to, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, modify the reference or combine the reference teachings; and 3) a reasonable expectation of success. MPEP 706.02(j). Applicants submit that not all of these requirements have been met.

As an initial matter, Applicants submit that the Carter et al patents, Patent Nos. 5,807,706; 5,821,333; 5,731,168 are not properly considered prior art under 35 U. S. C. 103 (c). The instant application is a continuation application of U.S. Application Ser. No. 09/070,166 filed April 30, 1998, which application claims priority under 35 U.S.C. 119 (e) to U.S. Application Ser. No. 60/046, 816, filed May 2, 1997. The Carter et al. 5,807,706 patent is a U.S. patent with a filing date of May 3, 1995 and an issue date of September 15, 1998. The Carter et al. 5,821,333 patent is a U.S. patent with a filing date of May 3, 1995 and an issue date of October 13, 1998. The Carter et al. 5,731, 168 patent is a U.S. patent with a filing date of May 3, 1995 and an issue date of March 24, 1998. These references qualify as prior art only under § 102(e).

A reference that is prior art only under § 102(e) cannot be used, according to § 103(c), in an obviousness rejection if the subject matter of the cited reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. A clear statement of entitlement to the prior art exclusion by Applicants or a registered practitioner is a sufficient evidence to establish the prior art exclusion (Examination Guidelines for 35 U.S.C. § 102(e) (as amended and revised) at IV(5); 1266 TMOG 80, January 14, 2003).

Applicants hereby make a clear statement of entitlement to exclude the Carter et al. patents as prior art as provided by § 103(c). The Carter et al. patents 5,807,706, 5,821, 333 and 5,731, 168 are assigned to the assignee of the present patent application. The Carter et al. patents 5,807,706, 5,821, 333 and 5,731,168, and the present patent application were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Applicants' claims 33-38 and 41-44 are directed to methods and host cells for preparing a bispecific antibody wherein the first and second variable light chain domain have at least 98% sequence identity and only differ in amino acid positions outside of the CDRs. Applicants' claims 36-38 and 43-44 are directed to host cells and methods for preparing a bispecific antibody, wherein each of the multimerization domains comprises a residue with a free thiol positioned so that a disulfide bond is formed between the first and second polypeptides. Applicants' claims 45-51 are directed to a method for preparing a bispecific antibody whereby a light chain variable domain is selected that has at least 98% sequence identity to each variable light chain domain of each of two different antibodies.

Production of conventional bispecific antibodies is inefficient due to unwanted pairing of heavy and light chains. Co-expression of two different antibodies may produce up to 10 heavy and light chain pairings which results in problematic purification and low yield of bispecific antibodies. Applicants' claims are directed to methods for preparing bispecific antibodies that are easier to purify and have increased yields. By selecting a light chain variable domain that has at least 98% sequence identity or has at least 98% sequence identity to each variable light chain of each of two different antibodies, the number of unproductive pairwise combinations is reduced. Applicants have shown that the identical or nearly identical light chains (at least 98% sequence identity) can be found in the majority of pairwise combinations. This frequency of finding identical light chains or light chains having at least 98% sequence identity shows it is feasible to more effectively produce bispecific antibodies using this strategy.

Mallender et al. disclose the preparation of a bispecific antibody constructed in a single polypeptide chain where each of variable heavy and light variable domains that form the different antigen binding sites are connected to one another in a single polypeptide chain. The method of Mallender is very different than that as claimed by Applicants. Because the bispecific antibody formed in Mallender is a single polypeptide chain where each antigen-binding site is connected via a peptide, Mallender does not contemplate a first and second polypeptide having multimerization domains that interact with one another. Such domains are not needed in the bispecific antibody of Mallender or are suggested by Mallender.

In addition, Mallender also does not contemplate a first and second variable light chain that have at least 98% sequence identity in amino acid positions outside of the CDRs and forming a bispecific antibody by the first variable light chain interacting with the first or second variable heavy chain and the second variable light chain interacting with the first or second variable heavy chain. In the method of Mallender et al, each of the variable light chains are linked in a single polypeptide chain to each corresponding variable heavy chain. The reference does not contemplate a first variable light chain interacting with the first or second variable heavy chain or the second variable light chain interacting with the first or second variable heavy chain. In fact , because of the covalent attachment of the heavy and light chains of Mallender, it may not be possible for the first or second variable light chain of Mallender to interact with the first or second variable heavy chain.

Mallender et al also is not concerned with the problem of yield of bispecific antibodies but rather is directed to showing that a single chain bispecific antibody can

retain dual specificity. The reference does not teach or suggest that a first and second light chain having at least 98% sequence identity at positions outside of CDRs, 98% sequence identity to each variable light chain of a first and a second antibody, or even 100% sequence identity should be selected so as to improve yield of bispecific antibodies.

Thus, Mallender et al. does not teach or suggest a method for preparing a bispecific antibody comprising a first polypeptide and a second polypeptide, nor a first polypeptide and a second polypeptide each with a multimerization domain that interact with one another. Because each of the heavy and light variable domains in Mallender et al. are linked via a peptide, this reference also does not teach or suggest that the first or second variable light chain may interact with either of the first or second heavy chain variable domains. Mallender et al is also silent regarding bispecific antibodies with a first and second light chain variable domain that have 98% sequence identity in amino acid positions outside of the CDRs or a variable light chain domain that has at least 98% sequence identity to each variable light chain domain of two antibodies that each bind a different antigen.

The Gulliver et al. reference does not remedy the defects of the Mallender et al reference. This reference is directed to the study of the role of heavy chain CDRs in antigen binding and the Examiner indicates that the reference discloses that two antibodies with different specificities have nearly identical light chains. This reference does not discuss bispecific antibodies or methods for forming bispecific antibodies. In particular, this reference does not teach or suggest a method for preparing a bispecific antibody comprising a first and second polypeptide, nor a first polypeptide and a second

polypeptide each with a multimerization domain that interact with one another, or light chains that have at least 98 % sequence identity. This reference is not concerned with bispecific antibodies and therefore, does not teach or suggest that variable light chains that have at least 98% sequence identity at amino acid positions out side of CDRs, 98% sequence identity to each variable light chain of a first and a second antibody, or even a 100% sequence identity should be selected over other light chains in a method to prepare a bispecific antibody.

The deficiencies of the Mallender et al. and Gulliver et al. references are not remedied by reference to U.S. Pat. Nos. 5,731,168-A, 5,807, 706-a, and 5,821,333-A. These references are not properly considered prior art.

Thus, Applicants submit even when all of the cited references are combined they do not teach or suggest all of the elements of the claimed invention. This combination of references does not teach or suggest a bispecific antibody comprising a first and second polypeptide, a first polypeptide and a second polypeptide each with multimerization domains that interact with one another, or a first and second variable light chain that have at least 98% sequence identity in a region outside of the CDRs or a selected variable light chain domain that has at least 98% sequence identity to each variable light chain domain of two antibodies that bind different antigens. At least for these reasons, Applicants submit that the Examiner has not established a prima facie case of obviousness.

Applicants submit that one of skill in the art would not be motivated to combine or modify the references as cited by the Examiner. The Mallender et al. reference is directed to forming a bispecific antibody in a single polypeptide where each light chain variable domain is paired with its original heavy chain domain because the light chain

variable domains and heavy chain variable domains are present in a single polypeptide. This reference is concerned with forming a single chain antibody and does not discuss the problem of yield of bispecific antibodies. In the method of Mallender, multimerization domains are not needed or suggested. In addition, Mallender does not teach or suggest the selection of first and second variable light chains that have at least 98% sequence identity at amino acid positions outside of CDRs, 98% sequence identity to each variable light chain of the first and second antibody, or even 100% sequence identity as a solution to increasing yield of bispecific antibodies.

As discussed previously, the Gulliver et al reference is directed to the study of the influence of heavy chain CDRs on antigen binding specificity of a single type of antibody. Since this reference does not suggest bispecific antibodies, there is no teaching or suggestion of a first and second polypeptide that interact via multimerization domains. In addition, Gulliver et al. does not teach or suggest the selection of first and second variable light chains that have at least 98% sequence identity or even 100% sequence identity as a solution to increasing yield of bispecific antibodies.

Based on the foregoing, Applicants submit that one of skill in the art would not be motivated to combine or modify these references to achieve Applicants' claimed invention.

Therefore, withdrawal of this rejection is respectfully requested.

2) **Claims 1, 8, 9, 11, 19, 20, and 30-44 stand rejected under 35 U.S.C. § 103 as unpatentable over Vaughan et al. in view of Bruynck et al. or Vuillez et al., and further in view of U.S. Pat. Nos. 5,731,168-A, 5,807,706-A, and 5,821,333-A.**

Applicants have canceled claims 1, 8, 9, 11, 19, and 20 rendering the rejection of these claims moot. Applicants respectfully traverse the rejection of claims 30-44.

In order to establish a prima facie case of obviousness, three basic criteria must be met, namely: 1) the references when combined must teach or suggest all of the claim limitations; 2) suggestion or motivation to, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, modify the reference or combine the reference teachings; and 3) a reasonable expectation of success. MPEP 706.02(j). Applicants submit that not all of these requirements have been met.

As discussed previously, U.S. Pat. Nos. 5,731,168-A, 5,807, 706-a, and 5,821,333-A are not properly considered prior art and will not be discussed herein.

Applicants' claims 30-32 and 38-39 are directed to a method and host cells for preparing a bispecific antibody wherein the first and second binding domains have the same light chain. Applicants' claims 33-38 and 41-44 are directed to methods and host cells for preparing a bispecific antibody wherein the first and second variable light chain domain have at least 98% sequence identity and only differ in amino acid positions outside of the CDRs. Applicants' claims 36-38 and 43-44 are directed to host cells and methods for preparing a bispecific antibody, wherein each of the multimerization domains comprises a residue with a free thiol positioned so that a disulfide bond is formed between the first and second polypeptides. Applicants' claims 45-51 are directed to a method for forming a bispecific antibody by selecting a variable light chain domain

that has at least 98% sequence identity to each variable light chain domain of two different antibodies that each bind a different antigen.

Production of conventional bispecific antibodies is inefficient due to unwanted pairings of heavy and light chains. Co-expression of two different antibodies may produce up to 10 heavy and light chain pairings which results in problematic purification and low yield of bispecific antibodies. Applicants' claims are directed to methods for preparing bispecific antibodies that are easier to purify and have increased yields. By selecting a light chain variable domain that has at least 98% sequence identity or has at least 98% sequence identity to each variable light chain of each of two different antibodies, the number of unproductive pairwise combinations is reduced. Applicants have shown that the identical or nearly identical light chains (at least 98% sequence identity) can be found in the majority of pairwise combinations. This frequency of finding identical light chains or light chains having at least 98% sequence identity shows that it is feasible to more effectively produce bispecific antibodies using this strategy.

The Vaughan et al. reference discloses and is directed to an scFv phage library of naïve antibody variable domains. The Vaughan et al. reference is directed to forming a diverse library of naïve antibody variable domains. The reference reports that the same light chain is sometimes paired with different heavy chains in antibodies with different specificities. However, this reference does not teach or suggest that such light chains should be selected over other light chains or that these light chains can or should be used in bispecific antibodies. There is no teaching or suggesting in Vaughan et al. that antibodies to different antigenic specificities but with identical light chains can be found at a high frequency. In addition, Vaughan et al. does not describe the use of

multimerization domains or that a first and second variable light chain domain can have at least 98% sequence identity in amino acid positions outside of CDRs in a bispecific antibody. Since this reference does not teach or suggest a method of obtaining bispecific antibodies, the reference does not teach or suggest selecting light chains having at least 98% sequence identity or even 100% sequence identity to prepare a bispecific antibody in high yield.

The deficiency of the Vaughan et al. reference is not remedied by reference to Bruynck et al. or Vuillez et al. Bruynck et al. discloses the generation of a bifunctional MAb possessing binding specificity for a tumor associated antigen (CEA) on one arm and for a radiolabelled chelate (DTPA) on the other arm. This reference does not discuss any problems with the formation of the bispecific antibodies and is not concerned with the pairing of light and heavy chains. Bruynck et al. does not teach or suggest formation of bispecific and oligospecific receptors by selecting a first and second variable light chain domain having at least 98% sequence identity in amino acid positions outside of CDRs or by selecting the same light chains. The reference also does not teach or suggest a method where the first variable light chain domain interacts with the first or second variable heavy chain and the second variable light chain interact with the first or second heavy chain. Nor does the reference teach or suggest the use of a multimerization region in a polypeptide to form a bispecific or oligospecific receptor.

Vuillez et al. discloses a bispecific anti-CEA/anti-di-DTPA antibody used to improve an immunoscintigraphy method for mediastinal staging of nonsmall cell lung cancer. This reference also does not discuss any problems with the formation of the bispecific antibodies and is not concerned with the pairing of light and heavy chains.

Vuillez et al. does not teach or suggest formation of bispecific and oligospecific receptors by selecting a first and second variable light chain domain having at least 98% sequence identity in amino acid positions outside of CDRs or selecting the same light chain. The reference also does not teach or suggest a method where the first variable light chain domain interacts with the first or second variable heavy chain and the second variable light chain interact with the first or second heavy chain. Nor does the reference teach or suggest the use of a multimerization region in a polypeptide to form a bispecific or oligospecific receptor.

Thus, Applicants submit even when all of the cited references are combined they do not teach or suggest all of the elements of the claimed invention. This combination of references does not teach or suggest a method for forming a bispecific antibody comprising a first and second variable light chain that have at least 98% sequence identity in a region outside of the CDRs , or a bispecific antibody comprising a first or second binding domain with the same light chain that has 98% sequence identity to each light chain variable domain of two different antibodies, or a bispecific antibody with multimerization domains. These references, when combined, also do not teach or suggest a method where the first variable light chain domain interacts with the first or second variable heavy chain and the second variable light chain interact with the first or second heavy chain. At least for this reason, Applicants submit that the Examiner has not established a prima facie case of obviousness.

Applicants submit that one of skill in the art would not be motivated to combine or modify the references as cited by the Examiner. The Vaughan et al. reference is directed to forming a diverse scFv phage library of naïve antibody variable domains. The

reference reports that the same light chain is sometimes paired with different heavy chains in antibodies with different specificities. The Vaughan et al. reference is directed to the problem of forming a diverse library of antibody variable domains using phage display. This reference does not describe bispecific antibodies or any concerns regarding the methods for producing bispecific antibodies in high yield. Thus, this reference does not teach or suggest that light chains that have at least 98% sequence identity or even 100% sequence identity should be selected over other light chains to improve yield of bispecific antibodies. Moreover, Vaughan et al. did not teach or suggest that ScFv with identical light chains could be found at a high frequency of possible pairwise combinations of antibodies with two different antigen specificities.

In addition, since Vaughan et al. is not concerned with bispecific antibodies it does not describe the use of multimerization domains or that a first and second variable light chain domain can have at least 98% sequence identity in amino acid positions outside of CDRs or that the same light chains for each binding domain should be selected for use in a bispecific antibody.

As discussed previously, the Bruynck et al., or Vuillez et al.. are directed to showing the functionality and dual specificity of specific bispecific antibodies. These references not directed to methods for preparing bispecific antibodies and do not teach or suggest selection of first and second variable light chains that have at least 98% sequence identity or even 100% sequence identity as a solution to increasing yield of bispecific antibodies.

In addition, since these references are not concerned with methods of forming bispecific antibodies they do not describe the use of multimerization domains or that a

first and second variable light chain domain can have at least 98% sequence identity in amino acid positions outside of CDRs in a bispecific antibody. Nor do they describe that the first variable light chain can interact with the first or second variable heavy chain and the second variable light chain can interact with the first or second variable heavy chain to form a bispecific antibody.

Applicants also submit that there would be no reasonable expectation of success that the claimed method would result in the efficient production of bispecific antibodies. The Vaughan et al. reference does not teach or suggest selecting light chain variable domains that have 98% sequence identity or even 100% sequence identity in a bispecific antibody. Although the Vaughan et al. reference discloses that the same light chain is sometimes paired with different heavy chains, there is no disclosure in Vaughan that a light chain having at least 98% sequence identity can be found at high frequency of pairwise combinations. The other cited references are not directed to methods for forming bispecific antibodies and also do not therefore teach or suggest a reasonable expection of success with Applicants' claimed methods.

Based on the foregoing, Applicants submit that one of skill in the art would not be motivated to combine or modify these references to achieve Applicants' claimed invention.

Applicants therefore, respectfully request withdrawal of this rejection of these claims.

3) **Claims 1, 8, 9, 11, 19, 20, and 30-44 stand rejected under 35 U.S.C. § 103 as unpatentable over Vaughan et al. in view of Reddy et al. and further in view of U.S. Pat. Nos. 5,731,168-A, 5,807,706-A, and 5,821,333-A.**

Applicants have canceled claims 1, 8, 9,11,19,and 20 rendering the rejection of these claims moot. Applicants respectfully traverse this rejection with respect to claims 30-44.

In order to establish a prima facie case of obviousness, three basic criteria must be met, namely: 1) the references when combined must teach or suggest all of the claim limitations; 2) suggestion or motivation to, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, modify the reference or combine the reference teachings; and 3) a reasonable expectation of success. MPEP 706.02(j). Applicants submit that not all of these requirements have been met.

As discussed previously, U.S. Pat. Nos. 5,731,168-A, 5,807, 706-a, and 5,821,333-A are not properly considered prior art and will not be discussed herein.

Applicants' have described the claimed subject matter above.

The Vaughan et al. reference discloses and is directed to an scFv phage library of naïve antibody variable domains. The reference reports that the same light chain is sometimes paired with different heavy chains in antibodies with different specificities. However, this reference does not teach or suggest that such light chains should be selected over other light chains or that these light chains can or should be used in bispecific antibodies. In addition, Vaughan et al. does not describe or suggest the use of multimerization domains or that a first and second variable light chain domain can have at least 98% sequence identity in amino acid positions outside of CDRs in a bispecific antibody or forming a bispecific antibody comprising a first and second binding domain

with the same light chain. Since this reference does not teach or suggest a method of obtaining bispecific antibodies, the reference does not teach or suggest selecting light chains having at least 98% sequence identity or even 100% sequence identity to prepare a bispecific antibody in high yield.

The remaining reference does not remedy these deficiencies. Reddy et al. teaches a method of producing a BsMAb recognizing both CEA and doxorubicin for site specific drug delivery. This reference does not discuss any problems with the formation of the bispecific antibodies and is not concerned with the pairing of light and heavy chains. Reddy et al., does not teach or suggest a method forming of bispecific and oligospecific receptors by selecting a first and second variable light chain domain having at least 98% sequence identity in amino acid positions outside of CDRs or selecting light chains that have the same sequence. The reference also does not teach or suggest a method where the first variable light chain domain interacts with the first or second variable heavy chain and the second variable light chain interact with the first or second heavy chain. Nor does the reference teach or suggest the use of a multimerization region in a polypeptide to form a bispecific or oligospecific receptor.

Thus, Applicants submit even when the cited references are combined they do not teach or suggest all of the elements of the claimed invention. This combination of references does not teach or suggest a bispecific antibody comprising a first and second variable light chain that have at least 98% sequence identity in a region outside of the CDRs, or a bispecific antibody comprising first and second binding domains that have the same light chain that has at least 98% sequence identity to each variable light chain of a first and second antibody, or first and second polypeptides that each have a

multimerization domain. At least for this reason, Applicants submit that the Examiner has not established a prima facie case of obviousness.

Applicants submit that one of skill in the art would not be motivated to combine or modify the references as cited by the Examiner. The Vaughan et al. reference is directed to forming a diverse scFv phage library of naïve antibody variable domains. The reference reports that the same light chain is sometimes paired with different heavy chains in antibodies with different specificities. However, this reference does not describe bispecific antibodies or any concerns regarding the methods for producing bispecific antibodies in high yield. Thus, this reference does not teach or suggest that light chains that have at least 98% sequence identity or even 100% sequence identity should be selected over other light chains to improve yield of bispecific antibodies. Moreover, Vaughan et al. did not teach or suggest that ScFv with identical light chains could be found in high frequency of possible pairwise combinations of two different antigen specificities.

In addition, since Vaughan et al. is not concerned with bispecific antibodies it does not describe the use of multimerization domains or that a first and second variable light chain domain can have at least 98% sequence identity in amino acid positions outside of CDRs in a bispecific antibody.

As discussed previously, the Reddy et al. reference is directed to showing the functionality and dual specificity of specific bispecific antibodies. This reference is not directed to methods for preparing bispecific antibodies and do not teach or suggest selection of first and second variable light chains that have at least 98% sequence identity or even 100% sequence identity as a solution to increasing yield of bispecific antibodies.

In addition, since this reference is not concerned with methods of forming bispecific antibodies it does not describe the multimerization domains or that a first and second variable light chain domain can have at least 98% sequence identity in amino acid positions outside of CDRs in a bispecific antibody. Nor do they describe that the first variable light chain can interact with the first or second variable heavy chain and the second variable light chain can interact with the first or second variable heavy chain to form a bispecific antibody.

Applicants also submit that there would be no reasonable expectation of success that the claimed method would result in the efficient production of bispecific antibodies. The Vaughan et al. reference does not teach or suggest selecting light chain variable domains that have 98% sequence identity or even 100% sequence identity in a bispecific antibody. Although the Vaughan et al. reference discloses that the same light chain is sometimes paired with different heavy chains, there is no disclosure in Vaughan that a light chain having at least 98% sequence identity can be found at high frequency of pairwise combinations. The other cited references are not directed to methods for forming bispecific antibodies and also do not therefore teach or suggest a reasonable expection of success with Applicants' claimed methods.

Based on the foregoing, Applicants submit that one of skill in the art would not be motivated to combine or modify these references to achieve Applicants' claimed invention.

Applicants therefore, respectfully request withdrawal of this rejection of these claims.

Interview

Applicants request an interview with the Examiner and his supervisor after receipt of these papers. The Examiner is requested to contact Applicants' representative to schedule the interview.

Summary

Applicants submit, therefore, that all pending claims are in condition for allowance, and notice to that effect is earnestly solicited. The Examiner is invited to contact Applicants' representative at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

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Date: Sept 25, 2003

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